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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/884,183

Applicant(s)

WEINSTEIN, BRET S.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a).

Applicant's appeal brief filed August 31, 2005 has been entered and noted. In the Appeals conference, it was decided that prosecution be re-opened to make rejections not previously made of record.

Claims 1-4 and 8-20 have been canceled. Claims 5-7 are pending and currently under examination.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

It is noted that throughout the specification and in particular on pages 31-35, multiple references are cited, and upon review of the submitted IDS some of the references have been provided, however not all have been formally submitted by Applicant. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is withdrawn.

Initially, it is noted that the specific method steps would be considered enabled because in the prior art of record clearly one could determine teleomere length, mate animals, and use animals in experiments. Further, it is noted that the present specification provides no new methodology for affecting teleomere length, rather relies on the inherent ability/properties of an animal. In light of this reasoning, the enablement rejection is withdrawn.

It is noted that the basis of the previous rejection focused on the failure of the present specification to provide the necessary guidance to use the claimed invention. More specifically, it was argued that while the specification attempts to make a correlation of teleomere length and specific diseases or uses in screening procedures, it fails to provide guidance on determining the specifics of determining what populations to choose, in particular providing a nexus between teleomere length and a specific use of or for a given teleomere length. Applicants arguments as represented in the appeal brief attempt to make a correlation citing art drawn to aging and diseases states, however it is noted by the Examiner that in each case teleomere length is not a causative factor, rather a consequence. Instead of teleomere length, other genotypic factors are

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important in determining the phenotype of a given animal. For a more general review of the state of the art at the time of filing see for example review of Festing (Neurobiology 20:23-244, 1999) who teaches the affects of breeding animals and the consequence of the genotype and phenotype. It is further noted that this is consistent with Applicant's own views that it is not telomere length by itself that may affect a phenotype, rather the mechanisms that control it (see Weinstein et al., Exp Gerontol. (2002 May) 37(5):615-27), and that the breeding of favorable phenotypes in laboratory animals may result in this loss of control. Importantly, it is noted that at the time of filing and today there exists multiple lines of inbred animals (mice, dogs, cats, cattle,...) and while one would acknowledge that there are phenotypic differences among various lines, none of the phenotypes are correlated with telomere length (for example the predisposition of one line of mice to diabetes or susceptibility to carcinogens).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 7 is inconsistent with the methods of breeding/making progeny required by claims 5 and 6, because in its literal interpretation of claim 7 requires that the one or more chromosomes contained in the germ cell of an animal in the first population be modified. To the literal interpretation of this embodiment, claim 7 appears to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are ones that are drawn to specifically modifying the telomere of one or more of

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the chromosomes contained in a germ cell of an animal. The claim is confusing and indefinite because the metes and bounds of claim 7 are not specifically set forth wherein one could determine what is being practiced/claimed. Since the specification appears to only support methods of mating to affect changes in telomere length, it is unclear how one would practice mating and result in a first population, not a second population, nor how this methodology affects less than all the chromosomes of any given cell much less only the germ cell of an animal. Absent any active method step(s), it would appear that the telomere length of a given animal in a first population is simply inherent to said animal.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee *et al.* (Nature 329:669-674, April 1998).

Claim 5 broadly encompasses selecting a population of animals, determining their telomere length and allowing them to breed to produce offspring. Similarly, claim 6 encompasses the same methodology except that the progeny has a distribution of telomere that is different from the first population as a whole. Neither claims 5 nor 6 have any active step wherein the telomere length is specifically modified, and given the guidance of the present specification requires simply the mating of two animals, and relying on the inherent property of

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the animal to result in any given type of progeny. To this end, claim 7 while reciting that the telomere length of the germ cell is altered, given the guidance of the specification and the art of record, this is again achieved only through mating, and while germ cell is recited would in fact result in, and in its breadth encompasses all the cells of the animal having a altered telomere length.

Lee *et al.* teach a mouse where the telomere length has been determined, and provide analysis of the mice for experimental purposes. Lee *et al.* provide a first population of mice and consecutive breeding of said progeny to provide six generations of offspring, and analyze the telomere length of each corresponding generation (see figure 1(1) for example). Further, Lee *et al.* analyze the correlation ion each generation of telomere length and affects on the reproductivie system, in particular the germ cells of both the female and male germ cells (see figures 1(d) and 2 for example).

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiels *et al.* (Nature 399:316-317, May 27, 1999).

The breadth of the claims are discussed above. While the instant specification teaches only methods of mating to achieve its goal of producing progeny, the art would also support the use of nuclear transfer, *i.e.* the cloning of an animal to produce an off-spring. Additionally, it is noted that there is no specific requirement for the order of practicing the method steps of claims 5 and 6, *i.e.* breeding can precede analysis of telomere length.

Shiels *et al.* teach the cloning of three sheep using nuclear transfer. Shiels *et al.* analyze the telomere length of the sheep relative to age matched donors. Shiels *et al.* conclude that the

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telomere length of the sheep is varied but shorter than that of another population. It is note that Shiels *et al.* analyze the length of telomeres in cells isolated from the blood, and does not specifically analyze the telomere length of the germ cell, however this would be considered to be inherent to the animals tested since the cells tested are representative of the rest of the animal. While the claims are drawn to methods in it noted that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Voitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

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AUG 82